

REMARKS

In a final office action dated April 27, 2005, claims 34 through 58 and 60 - 80 were rejected. Reconsideration of the claims in view of the amendments to the claims and the following remarks is respectfully requested.

Claims 1 through 33 have been previously withdrawn from examination.

Independent claims 34, 61, 66, and 71 have been amended to specify amounts and/or properties of the organic acid. In particular, the organic acid is said to be present in the solution in an amount of at least 0.5% by weight of the solution and to have a pKa of no greater than about 5. As will be discussed below, the effect of this is to require that the organic acid solutions be relatively strong in organic acidic. As will be shown, solutions having a pH of below 4 result from these limitations. Independent claim 76 has been amended to recite this pH requirement. Additional claims, including both the pH and the pKa / amount requirements are also set forth in the present amendments. Support for the amendments can be found throughout the specification where stability of the components of the solution to strong acid is described within the context of the intended uses. Moreover, concentrations of organic acids having known pKa values are set forth. From this, the respective pH values of the organic acid solutions may be calculated directly. No new matter has been added.

The present invention is directed to irrigation solutions comprising disinfectant, detergent, and organic acid in amounts effective to remove smear layers from dental, endodontic, periodontal or orthopaedic preparations. As is apparent from the specification, strong organic acid solutions are needed for this invention. To this end, a number of exemplary organic acids are described in terms of their pKa and amount by weight in the

solutions. From this may also be determined the pH of the respective solutions. In all cases, a pH of 4 or less, indicating strong acidity, is called for. As will be seen, the prior art does not disclose any of these requirements. Indeed, in the principal art cited, **avoidance** of strongly acidic solutions is taught; adjustment to higher pHs is called for.

The invention provides the first truly effective and practical means for removing “smear layer” from prepared tooth surfaces, endodontic surfaces, periodontal surfaces and orthopaedic surfaces. The term “smear layer” is well known in the endodontic art and refers to the build-up of organic and inorganic debris that results from mechanical preparation of a tooth or bone surface. Complete or near-complete removal of such layers has long been a goal of practitioners in these fields, with varied results. The present invention, however, is the first solution to combine a disinfectant, a detergent, and an organic acid in an amount and having a strength to confer the level of organic acid acidity which, in combination with the other components, effectively removes smear layers consistently and easily from prepared surfaces. The solution also simultaneously results in sterilization of these surfaces.

While components of the present solution have previously been used individually or as part of other combinations, the presently required components with the presently required acidities are believed not to have been used together to remove smear layers and are believed not to have been combined in proportions effective for this application. Additionally, previous solutions used to remove smear layers have been only partially effective, often leaving behind debris and bacteria that hinders the healing process for patients undergoing endodontic, dental, periodontal, or orthopaedic procedures. In contrast, the present invention effects substantially complete removal of the smear layer and sterilization of a prepared

surface in a very short amount of time, an unexpected result far superior to any irrigation solution previously known in these fields.

The superiority of the present invention was recognized almost immediately by experts in the endodontic field. Notably, articles describing a product made in accordance with the present invention were featured in back-to-back issues of the field's leading journal, the *Journal of Endodontics*. Copies of articles from March 2003 and April 2003 *Journal of Endodontics* were previously submitted. Subsequently, seven more articles were published in the same journal during the year 2003 and others have followed. Those articles demonstrate the antibacterial effectiveness and biocompatibility of the solutions described herein. Additionally, the present invention was the subject of a presentation for an audience of over 1000 endodontists at the American Association of Endodontists 2003 Annual Session. Moreover, a product in accordance with the invention has now been approved by the U.S. FDA (510(k) number K032361). Accordingly, while seemingly simple, the present invention has achieved immediate recognition. It is a true advance in the art.

The invention provides novel, sterile solutions having disinfectant, preferably antibiotic, surfactant and acid together with methods for using them. The solutions are formulated to be very acidic; e.g. to have pHs less than about 4, and preferably even lower. This acidity requirement is reflected in two, alternative ways of expression. Either the pH is called for directly, determined from the readily calculated pH values for organic acids listed in the specification, or a minimum amount and pKa value for the acids are specified. The resulting solutions have short term stability sufficient to effect the removal of smear layers from prepared surfaces. Unlike the situation in the cited art, Akazawa, there is no particular need to maintain long term shelf stability for these solutions as they are generally used

quickly once formulated. Stability of the components only within the relatively short time frame of the indicated uses is all that is required here.

The claims have been rejected in view of United States Patent No. 3,846,548 (“Akazawa”). The Examiner holds the view that Akazawa shows solutions having the recited components of those now claimed, albeit in greater amounts, and that, accordingly, Akazawa would necessarily have an “effective amount” of those components. While the Examiner agrees that Akazawa does not suggest the utility of the present sterile solutions, the recited utility is viewed by the Examiner as not conferring patentable distinction in a composition of matter claim.

The present amendment requires that the sterile solutions of the invention comprise organic acid having a pKa of no greater than about 5 in amounts of at least about 0.5% by weight of the solution. With the kinds of organic acids described, this yields pH values for the organic acid containing solutions of 4 or less. The limitation of the solutions as regards acid properties and amounts is important to effective operation of the solutions to give the desired smear removal properties. This stands in stark contradistinction to Akazawa, where long term stability of pharmaceutical solutions is desired. To that end, the solutions of Akazawa are adjusted so that their pH is between 5.0 and 7.0. See, e.g., column 1 lines 27-28 and column 2, lines 66 et seq.. It is clear that in the context of the shelf storage stable solutions desired by Akazawa, lower pH is avoided. Indeed, beginning with the background section of Akazawa, lability of the doxycycline compositions to highly acid conditions is discussed. And that “. . . these solutions are found not to be suitable . . . “. Akazawa is simply not apposite.

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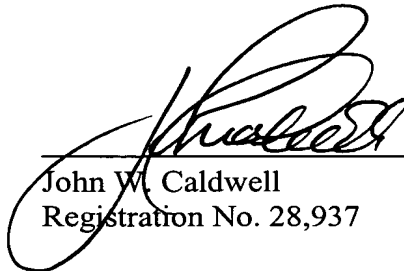
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It is noted, with thanks, that the rejection in view of the Chen reference has been withdrawn.

Examiner Jagoe is reminded of the existence of a pending application assigned to her and related to the present one, Serial No. 10/348,298, filed January 21, 2003. In that application, the examiner has issued a recent action. As in the present case, Akazawa was cited. However, an additional reference, Barkhordar, et al. Oral Surg. Oral Med. Oral Pathol. Oral Radiol. Endo. Vol 84, 420 - 423 (1997) was also cited. A copy of this reference was also provided in the present application along with an IDS. Barkhordar was discussed in the present specification and Applicants are of the view that Barkhordar is not particularly relevant here. Barkhordar focuses upon an inorganic acid formulation of doxycycline, doxycycline HCl. It does not suggest the use of solutions wherein organic acid is employed as required by the presently pending claims.

Applicants have distinguished over the art. It is respectfully submitted that the foregoing arguments and amendments place this application in condition for allowance. Applicants invite the Examiner to contact the undersigned at (215) 568 - 3100 to clarify any unresolved issues raised by this response.

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